Sorrento Therapeutics Logo

Scilex Holding, a Subsidiary of Sorrento Therapeutics, Announces Phase 2 Trial Results for its Leading SP-102 Program

March 26, 2019

- Complete Enrollment of Phase 2 Trial to Characterize the Pharmacodynamics and Safety of Repeat Dose SP-102 Administered by Epidural Injection in Subjects with Lumbosacral Radiculopathy, a.k.a. sciatica
- All subjects experienced rapid reduction of leg and back pain following two SP-102 injection treatments, with group median for average pain in affected leg reduced over 50% throughout 28 days for each injection (100% response rate). There were no serious adverse events observed
- The current pivotal Phase 3 trial (fast track status) is proceeding as planned and has already reached near 50% enrollment completion
- Scilex expects SP-102 to be the first FDA approved non-opioid epidural injections for sciatica with the potential to replace the current 10 to 11 million off-label epidural steroid injections administered each year in the U.S.

MOUNTAIN VIEW, Calif., March 26, 2019 (GLOBE NEWSWIRE) -- Scilex Holdings, Inc. (“Scilex”), a majority owned subsidiary of Sorrento Therapeutics, Inc. (NASDAQ: SRNE, "Sorrento"), today announced results of a Phase 2 trial (SP-102-03), an open-label, single-arm, pharmacodynamic and safety study of repeat epidural injections of SP-102 in patients with lumbosacral radicular pain (sciatica). The trial was conducted, as part of FDA requirements for NDA submission, to characterize repeat dose pharmacodynamics (PD) with respect to hypothalamic-pituitary-adrenal (HPA) suppression using plasma cortisol levels, white blood cell count (WBC), and blood glucose levels.

SP-102 is the first non-opioid novel injectable gel formulation in development for the treatment of lumbar radicular pain, containing no neurotoxic preservatives, surfactants, solvents or particulates. The SP-102 formulation is administered by epidural injection. Based on preclinical and clinical studies, it extends the residency time at the site of injection and does not show the safety concerns that led the FDA to warn against using other steroid formulations by epidural route of administration.

This Phase 2 trial enrolled 19 subjects, of which 15 received repeat SP-102 epidural injections 4 to 8 weeks after the index injection. All subjects experienced a reduction in daily leg and back pain measured by the Numeric Pain Rating Scale (NPRS) following both injections, with group means and medians for daily average, current and worst pain in the affected leg mostly demonstrating reductions by over 50% throughout the 28-day observational period for both treatments. All injections were well-tolerated. There were no serious adverse events. Comparison of PD effects demonstrated no apparent differences between first and second injections. Duration of cortisol suppression time was similar between the two treatments and lasted up to 5 days. There were no differences in the magnitude of transient increases of WBC and blood glucose levels between injections.

“In my clinical practice, patients with sciatica often receive repeat epidural injections. It is important to see that SP-102 cortisol suppression time is similar between two injections and would not interfere with clinical decisions about the administration of repeat doses. My experience with SP-102 in this trial has been positive from both an efficacy and safety standpoint and I look forward to possibly having a new treatment option to offer my patients.” – said Principal Investigator Dr. Richard Radnovich at Injury Care Research in Boise, ID.

“We are pleased to complete another trial in the SP-102 development program, with consistent data contributing to our NDA filing and providing instructive information for interventional pain physicians, who are waiting for FDA-approved steroid for epidural injections. We are also pleased to see the duration of pain relief lasting throughout 4 weeks following a single administration of SP-102. These results are consistent with our previous PK/PD bridging bioequivalence study (ES-1504) and confirm the principle behind the invention of viscous injectable gel dexamethasone regarding the extension of its local effect.” – said Dr. Dmitri Lissin, Chief Medical Officer.

“We believe these Phase 2 data validate our novel program and bolster our confidence that SP-102 can provide radicular pain/sciatica patients with persistent and prolonged pain relief. Lumbar radicular pain, otherwise known as sciatica, is commonly treated by off-label epidural steroid injections. There are an estimated ten to eleven million epidural steroid injections administered per year in the U.S. alone and there are no approved steroids for epidural injections.[1] These clinical results are our first seminal milestone for Scilex and provide encouraging news for the many millions of people who are confronting debilitating radicular pain/sciatica. We believe that SP-102 could be the first approved non-opioid treatment option for patients suffering from this common, painful condition,” said Jaisim Shah, President and Chief Executive Officer of Scilex Holdings.

Currently, SP-102 is also in a pivotal Phase 3 clinical trial in the U.S. to evaluate patients with lumbar radicular pain/sciatica. The CLEAR (“Corticosteroid Lumbar Epidural Analgesia for Radiculopathy”) Clinical Study is a randomized, double-blind, placebo-controlled Phase 3 trial that will enroll 400 patients with lumbar radicular pain at 40+ sites across the U.S.. The primary endpoint of the study is mean change in the NPRS for leg pain with SP-102 epidural injection compared to intramuscular injection of placebo over four weeks. The secondary endpoints include other measures of pain at 4 and 12 weeks as well as time to repeat injection of SP-102, safety and function. The study includes an open-label extension to build the safety database of patients treated with SP-102.

In the U.S., more than 30 million people live with low back and radicular pain, with this population expected to grow as the population ages.[3,4] Many patients experience moderate to severe pain with intolerance and/or inadequate response to current analgesic therapies such as opioids and nonsteroidal anti-inflammatory drugs (NSAIDs).[5,6] There is a great need for highly effective analgesic medications to provide patient relief without the toxicity and tolerability challenges of NSAIDs and opioids.[4] Opioid prescriptions account for about 40 percent of the chronic pain market and carry a well-known risk of abuse and misuse, underscoring the need for alternative pain therapies without the medical and societal challenges.[4,7]

Chronic pain affects 116 million, or almost one- in-three, Americans.[8] costs the United States approximately $560 to $635 billion annually and nearly 30 million patients suffer from lower back pain in the U.S..[9] Government agencies, physicians, patients, and payers are looking for alternatives to

opioids to reduce the risk of dependency or addiction, and serious side effects (such as respiratory depression and constipation), while still offering potent solutions for people living with chronic pain.

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to turn malignant cancers into manageable and possibly curable diseases. Sorrento's multimodal multipronged approach to fighting cancer is made possible by its' extensive immuno-oncology platforms, including key assets such as fully human antibodies ("G-MAB™ library"), clinical stage immuno-cellular therapies ("CAR-T"), intracellular targeting antibodies ("iTAbs"), antibody-drug conjugates ("ADC"), and clinical stage oncolytic virus ("Seprehvir®").

Sorrento's commitment to life-enhancing therapies for cancer patients and Osteoarthritis (OA) patients is also demonstrated by its effort to advance Resiniferatoxin ("RTX"), a first-in-class (TRPV1 agonist) non-opioid pain management small molecule, ZTlido® and SP-102, a non-opioid corticosteroid gel. Resiniferatoxin is completing a Phase 1b trial in terminal cancer patients and a Phase 1b trial for OA. ZTlido was approved by US FDA on 02/28/18. SP-102 is in Phase 3 pivotal study for the treatment of lumbar radicular pain/sciatica.

For more information visit www.sorrentotherapeutics.com

About Scilex Holding Company.

Scilex Holding Company, a majority-owned subsidiary of Sorrento located in San Diego, California, responsibly develops and brings branded products to market using technologies designed to maximize quality of life for the patientsit serrves.. We are uncompromising in our focus to become the global pharmaceutical leader in pain management through social, environmental, economic and ethical principles. Scilex's product, ZTlido® (lidocaine topical system 1.8%), is a branded lidocaine topical system formulation for the treatment of relieving the pain of post-herpetic neuralgia, also referred to as after-shingles pain. For more information, visit www.scilexpharma.com.

Semnur Pharmaceuticals, Inc., a wholly owned subsidiary of Scilex Holding Company. located in Mountain View, California, is a clinical-stage specialty pharmaceutical company, focused on the development and commercialization of best in class novel non-opioid pain therapies. Semnur's lead program, SP-102, is a non-opioid novel gel formulation administered epidurally in development for patients with moderate to severe chronic radicular pain/sciatica. For more information, visit www.semnurpharma.com or www.clearbackpainstudy.com.

SP-102 is a non-opioid corticosteroid formulated as a viscous gel injection, designed to prolong its analgesic effect at the site of the epidural injection, as demonstrated in clinical and preclinical studies. SP-102 does not contain neurotoxic preservatives, surfactants, solvents or particulates, which is expected to result in a better safety profile than commonly used off-label injected corticosteroids. Semnur's successful Phase 1/2 bridging study in patients with lumbar radicular pain achieved its primary pharmacokinetic endpoint of an extended product residency time at the site of injection, as well as demonstrated that a single injection of SP-102 led to over 30% improvement in leg and back pain over 30 days. Semnur's pivotal Phase 3 CLEAR trial is designed to satisfy regulatory requirements for a 505(b)(2) new drug application with the FDA.

Forward-Looking Statements

This press release and any statements made for and during any presentation or meeting concerning the matters discussed in this press release contain forward-looking statements related to Sorrento Therapeutics, Inc. and its subsidiaries, including but not limited to Scilex Holding Company, Scilex Pharmaceuticals, Inc. and Semnur Pharmaceuticals, Inc. under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding the outcome of the data from a clinical trial for SP-102, Scilex Holding's and Semnur's prospects, future clinical trials and the results thereof, market and patient population trends, and ability to accelerate the development of their lead program in the clinic. Risks and uncertainties that could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to that SP-102 may not meet all endpoints of the clinical study and that the data may not support an NDA submission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release and we undertake no obligation to update any forward-looking statement in this press release except as may be required by law.

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SEMDEXA™ (SP-102) is a trademark owned by Scilex Holdings. A proprietary name review by the FDA is planned.

Source: Sorrento Therapeutics, Inc.